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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/030,985	02/26/98	FALO JR	214001-00648

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DIANE R MEYERS
ECKERT SEAMANS CHERIN & MELLOTT
600 GRANT STREET
42ND FLOOR
PITTSBURGH PA 15219

EXAMINER	
PELLEY,R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/16/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/030,985	Falo And Celluzzi
Examiner	**Group Art Unit**
Ronald Pelley	1644

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *30 days* ~~month(s)~~, or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-36* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-36* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. **Please note**. In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is (703) 305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Supervisory Patent Examiner at Paula.Hutzell @ uspto.gov or (703) 308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 CFR121:

Group I, claims 1-12, drawn to a formulation and pharmaceutical composition comprising a hybridoma of an antigen processing cell and a tumor cell or virally infected cell, classified in class 424, subclass 93.7.

Group II, claims 13-24, drawn to a formulation and pharmaceutical compositons comprising the products of co-culture of an antigen processing cell and a tumor cell or virally infected cell, classified in class 424, subclass 184.1.

Group III, claims 25-30, drawn to a method of treating a patient to stimulate a CTL response comprising administration of a hybridoma of an antigen processing cell and a tumor cell or virally infected cell, classified in class 424, subclass 93.7.

Group IV, claims 31-36, drawn to a method of treating a patient to stimulate a CTL response comprising administration of the products of co-culture of an antigen processing cell and a tumor cell or virally infected cell, classified in class 424, subclass 184.1.

3. Inventions I and II are different compositions of matter since the one comprises hybrid cells and the other comprises the product of mixed cells in culture.

4. Inventions III and IV are different methods of treatment. Invention III is drawn to the stimulation of a CTL response using hybrid cells whereas Invention IV is drawn to the use of products of cell co-culture.

5. Inventions I-II and III-IV are related as products and methods of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the products as claimed can be used in materially different processes, such as inducing the formation of antibodies.

6. Because these inventions are distinct for the reasons given above and the search required for products of co-culture is not required for hybridomas and because each Group has acquired a

separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is further required under 35 U.S.C.121:

If Group I or Group II are elected,
(a) to elect a specific species of antigen presenting cells recited in claims 1-2 or 13-14 and a specific species of antigenic second cells recited in claim 1 & 3-4 or claims 13 & 15-16.
(b) to list all claims readable thereon including those subsequently added. Currently claim 1 in Group I and claim 13 of Group II are generic.

If Group III or Group IV are elected,
(a) to elect a specific species of antigen presenting cells recited in claims 25-26 or 31-32 and a specific species of antigenic second cells recited in claim 25 & 27-28 or claims 31 & 33-34.
(b) to list all claims readable thereon including those subsequently added. Currently claim 25 in Group III and claim 31 of Group IV are generic.

(c) should applicant traverse items 7(a) on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. The antigen presenting cell species of Group I-IV, claims 1-2, 13-14, 25-26 and 31-32 are distinct because they are derived from different tissues by different methods of isolation, have different differentiation markers and are cultured under different conditions.

The tumor cell species of Group I-IV, claims 1 & 3 or 13 & 15 or 25 & 27 or 31 & 33 are distinct because they arise in different tisssues from embryologically different precursors and have distinct antigenic markers.

The virally-infected cell species of Group I-IV, claims 1 & 4 or 13 & 16 or 25 & 28 or 31 & 34 are distinct because they grow in different cultured cells of different origins, have differing types and sizes of nucleic acids, have distinct antigens and cause differing diseases with different vaccination regimens.

9. A telephone call was made to Diane Meyers on October 30th., 1998 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald P. Pelley whose telephone number is (703) 308-9343. The examiner can normally be reached Monday through Friday from 8:30 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner is Christina Chan at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Ronald P. Pelley, Ph.D.
Patent Examiner
Group 1640

CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP 1800 1640